UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/319,736	08/02/99	WOLPERT	E	000500-182

021839
BURNS DOANE SWECKER & MATHIS
P O BOX 1404
ALEXANDRIA VA 22313-1404

HM22/0316

EXAMINER	
HICKEY,K	
ART UNIT	**PAPER NUMBER**
1635	6

DATE MAILED: 03/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/319,736	Wolpert et al.
Examiner	**Group Art Unit**
Karen A. Lacourciere	1635

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-12 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed June 11, 1999 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered copies of the documents listed were not provided.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Something which occurs in nature, and is substantially unaltered, is not considered to be an item of "manufacture" (see MPEP 706.03(a)) and, therefore, is unpatentable. Claims 6 and 7 read on any cells which are impaired in cellular peptide processing and claim 8 reads on any

lymphoid cells, including such cells as they occur *in vivo,* made by a process of nature, and, therefore, would be non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claims 1-3 provide for the use of substances which impair cellular peptide processing, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a

process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 4 provides for the use of antigens and epitopes associated with impaired peptide processing, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 4 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 5 provides for the use of molecules directed against MHC class I antigens or epitopes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 5 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e.,

results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 6 recites the broad recitation "impaired cellular peptide processing", and the claim also recites "especially MHC class I dependent" which is the narrower statement of the range/limitation. This occurs in the first two lines of claim 6 and in the 7th and 8th lines of claim 6.

In the present instance, claim 6 recites the broad recitation "immunological effectors", and the claim also recites "especially CD8+ cells" and "preferably cytotoxic cells" which are narrower statements of the range/limitation.

In the present instance, claim 7 recites the broad recitation "mammalian cells", and the claim also recites "especially cells from the origin of a cancer" which is the narrower statement of the range/limitation.

In the present instance, claim 8 recites the broad recitation "Lymphoid cells", and the claim also recites "preferably CD8+ T-lymphocytes" which is the narrower statement of the range/limitation.

In the present instance, claim 8 recites the broad recitation "impaired cellular processing", and the claim also recites "especially MHC class I dependent" which is the narrower statement of the range/limitation.

In the present instance, claim 9 recites the broad recitation "impaired cellular processing", and the claim also recites "especially MHC class I dependent" which is the narrower statement of the range/limitation.

In the present instance, claim 10 recites the broad recitation "impaired cellular processing", and the claim also recites "especially MHC class I dependent" which is the narrower statement of the range/limitation.

In the present instance, claim 11 recites the broad recitation "impaired cellular processing", and the claim also recites "especially MHC class I dependent" which is the narrower statement of the range/limitation.

In the present instance, claim 12 recites the broad recitation "impaired cellular processing", and the claim also recites "especially MHC class I dependent" which is the narrower statement of the range/limitation.

Regarding claims 7-12, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 7-12, the phrase "for example" (abbreviated as "e.g.") renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 6-8 are indefinite because of the absence of an article in the preamble of the claim, rendering the scope of the preamble indefinite. The claims appear to follow the European style, whereas in U.S. practice independent claims normally contain an article in the preamble.

Claim 9 is indefinite because the preamble recites a process for induction of epitopes or antigens in mammalian cells, however step (e) of that process recites performing such induction in non-mammalian cells.

Claim 9 is indefinite because it recites a process for induction of antigens or epitopes, however the steps recited in such process (a-f) appear to each comprise a separate method. As such, it is unclear what the process being claimed actually is.

Claim 9 is indefinite because of the recitation "that take place" (page 38, line 27) and "that takes place" (p 39, line 4). The context of these phrases is not consistent with proper English and it is not clear what limitation the phrases are meant to provide to the substances to which they refer.

Claim 9 is indefinite because of the recitation "ribozyme destroying RNA". It is unclear what type of RNA is capable of destroying a ribozyme.

Claim 9 is indefinite because of the recitations "transfected" and "transfection". Transfection is an art term which refers to a process of putting an expressible piece of DNA into a cell. As written, claim 9 step e indicates "transfecting" with a protein. It is unclear if step e is actually transfecting with the gene for such protein or if the term transfection was not translated

properly. The context in which transfected/transfection has been used, also makes it difficult to determine if the word is proper. Specifically, it is not typical to refer to cells "to which" a gene has been transfected, nor is it typical to say "cells, transfection thereof".

Claim 12 is indefinite because it recites a process for treatment, prevention and diagnosis of cancer and viral infections, however, the steps recited in such process (a-f) appear to each comprise a separate method. As such, it is unclear what the process being claimed is.

Claims 9 and 12 recite a method for inducing antigens or epitopes and a method of treatment, prevention and diagnosis, respectively. Such methods are incomplete as there is no step in each method which relates back to the outcome set forth in the preamble. This is particularly relevant to the method of claim 12, as three different outcomes are set forth for the method and it is unclear which steps are performed to accomplish each objective.

The claims as originally presented are replete with errors, as noted above, and it is recommended that the applicant cancel all claims and submit new claims which conform with U.S. patent practice and more clearly represent the invention.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Nair et al.

Claims 6-12 are drawn to cells expressing antigens or epitopes associated with impaired cellular peptide processing, a process for inducing such antigens or epitopes, a kit which comprises a substance which induces such antigens or epitopes, a pharmaceutical composition comprising a substance which induces such epitopes or antigens and methods of treatment which induce such antigens or epitopes.

Nair et al. teach TAP-2 deficient cells RMA-S, treating TAP-2 deficient cells with antisense oligonucleotides directed at TAP-2, and administering such treated cells to mice to promote protection of said mice from injected tumor cells. Results presented by Nair et al. demonstrate that administering TAP-2 antisense to RMA-S cells results in a loss of expression of MHC class 1 on the cells surface, which would result in cells which appear to be impaired in cellular peptide processing. As such, Nair et al. anticipates claims 6-12.

Claims 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Franksson et al.

Franksson et al. teach TAP-2 deficient RMA-S cells treated with tumor antigen which stimulates antigen specific cytotoxic T cells. As such, Franksson et al. anticipates claims 6-9.

Any inquiry concerning this communication should be directed to Karen A. Lacourciere at telephone number (703)308-7523.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliot can be reached at (703) 308-4003. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

George C. Elliott, Ph.D.
Supervisory Patent Examiner
Technology Center 1600

Karen A. Lacourciere
March 7, 2000